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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,287	11/21/2003	Bruce A. Firestone	3123	3181

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EXAMINER	
OH, SIMON J	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,287	FIRESTONE ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-18 and 20-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-18 and 20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10, 11, 13-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over VESANOID (from the Physician's Desk Reference) in view of Cho *et al.* (U.S. Patent No. 5,656,289)

VESANOID is a retinoid which is available from Roche Laboratories in 10 mg soft gelatin capsules for oral administration. Each capsule contains butyated hydroxyanisole, vegetable oils, and other additives. In addition, the capsule shell contains several well-known colorants that impart color and opacity such as red iron oxide, yellow iron oxide and titanium dioxide (See bottom of Page 2).

VESANOID does not contain the specific additives as claimed by the applicant, such as the triglyceride or the specific emulsifiers.

The Cho *et al.* patent teaches an orally administrable formulation of a biologically active material comprising a water-in-oil emulsion (See Abstract). The Cho *et al.* further teaches that the hydrophobicity or the hydrophilicity of the active ingredient is not particularly critical in this composition (See Column 3, Lines 48-50). The reference further teaches that surfactants such as sorbitan monooleate, polysorbates, and vegetable oils, such as sesame oil or corn oil, are useful

in the invention (See Column 7, Line 62 to Column 8, Line 15). Further, he teaches that mixtures of surfactants can often be used in place of a single surfactant (See Column 9, Lines 18-20). The patent also teaches that it can be desirable to incorporate emulsification aids, which can also be surfactants, such as Polysorbate 80 (See Column 10, Lines 25-38). Further, the Cho *et al.* patent teaches that preservatives like antioxidants can be useful in the formulation (See Column 10, Lines 56-67). The reference specifically teaches butylated hydroxyanisole as an antioxidant for use in the formulation (See Column 11, Line 1). Lastly, the Cho *et al.* patent teaches that it is possible and sometimes preferable to formulate the solid or liquid formulations in order to provide passage through the stomach. For example, a liquid formulation may be mixed with a medium chain triglyceride and then filled into an enteric coated capsule (See Column 14, Lines 10-17).

One of ordinary skill in the art would have been motivated to combine the teachings of Cho *et al.* with the VESANOID formulation. The VESANOID formulation gives a specific orally administrable example of a drug that falls within the group of retinoids, which are traditionally known to be useful only in topical formulation. However, the VESANOID formulation teaches one very specific orally administrable capsule formulation comprising one specific retinoid. The Cho *et al.* patent teaches a generic formulation that can be used with many different drugs and may also be formulated into an enteric embodiment, so as to pass through the stomach without dissolving. One of ordinary skill in the art would have been motivated to look to a reference such as Cho *et al.* when formulating orally administrable capsules of a drug, specifically because Cho *et al.* teaches that the drug and its hydrophobicity or hydrophilicity is not critical to the success of the disclosed invention. One of ordinary skill in the art would

reasonably expect a successful pharmaceutical formulation that contains a retinoid and has enteric release properties to allow passage through the stomach. Therefore, the instantly claimed invention is prima facie obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10-18 and 20-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-24 of U.S. Patent No. 6,248,354 and Claims 1-9 of U.S. Patent No. 6,656,500. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention encompasses the scope of the subject matter of the '354 patent and the '500 patent. The instant claims and the claims of the '354 patent and the claims of the '500 patent are all drawn to a capsule composition for oral delivery, comprising a retinoid, a vehicle for dissolving the active agent, a capsule shell,

and an emulsifier. The instant claims and the claims of the '354 patent recite the same additives such as antioxidants as well as specific emulsifying agents. The claims of the '500 patent also recite the same specific emulsifying agents.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sjo

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER